



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,283	06/14/2001	Robert J. Crowley	BSC-031CN	7430
21323	7590	05/05/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			JUNG, WILLIAM C	
			ART UNIT	PAPER NUMBER
			3737	
DATE MAILED: 05/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,283

Applicant(s)

CROWLEY, ROBERT J.

Examiner

William Jung

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-24, 26-32, 44-47 and 49-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 11, 14-24, 26-32, 44-47, 54, 57-64, 66-74, 80, 87 and 88 is/are rejected.
- 7) ☒ Claim(s) 8-10, 12, 13, 49-53, 55, 56, 65, 75-79, and 81-86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-88 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

Claim Objections

2. Claims 1-4, 6-24, 26-32, 44-47, and 49-88 are objected to because of the following informalities: Throughout the claims, it is unclear as to whether the limitation "probe" such as in claim 1 means "probe array" as in element 11, as cited in page 3, or, "probe material" as in element 23. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 3737

4. Claims 1, 4, 6, 7, 11, 14, 15, 17-23, 26, 31, 32, 44, 47, 54, 57, 59-64, 66-69, 71, 80, 87, and 88 are rejected under 35 U.S.C. 102(e) as being anticipated by *Kovacs et al* (US 5,833,603).

Claims 1, 4, 31, 32, 44, 47, 54, 57, 59-63, 66-69, 71, and 80: Kovac et al anticipate all claimed features in claims 1, 4, 31, 32, 44, 47, 54, 57, 59-63, 66-69, 71, and 80. Kovac et al disclose an implantable biosensing transponder including substrate, 40 (figure 1), excitation source capable of generating radiation in a form of an optical emitter (col. 10, lines 28-45, probe in a form of a dye filled member, in path of radiation, probe contact a fluorescently-labeled analyte, such as tissue, blood, or cerebrospinal fluid, as in 4 (figure 3, element 56 and col. 10, lines 3-28). In addition, the biosensor transponder includes detector for detecting optical property of the probe to convert detected optical signals to electric signals in a form of photosensors (col. 10, line 49). The housing or capsule 44 house the excitation source, probe, and detector (col. 10, lines 24-26).

Claim 11: Kovac et al's apparatus also includes optics that affects the path of the radiation via lens (col. 13, lines 10-16).

Claims 14 and 15: Kovac et al's apparatus also includes processor to process the detected signals and amplifier to amplified the detected signals (col. 13, lines 5-15; col. 16, line 5).

Claims 6, 7, 17-23 and 64: Kovac et al's apparatus also includes spectrometer and LED encapsulated in transparent housing with LED source providing wavelength within 250-1100nm range (col. 11, lines 48-50; col. 12, line 40). Furthermore, Kovac et al's apparatus includes Photodiode and light detection system capable of detecting light at multiple wavelengths (col. 11, lines 55-65).

Claims 26, 87, and 88: Kovac et al 's apparatus is a catheter that carries the body insertable device to an area of interest, such as guidewire (figure 12, col. 18, lines 15-35).

5. Claims 1, 27-29, 30, 44, 72, and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by *Sun et al* (US 6,122,536).

Sun et al teach an implantable sensor including a substrate in a form of insulin (col. 10, lines 5-10), an excitation source (col. 10, line 55), a probe in a form of glucose being attached to the insulin substrate and disposed in the path of radiation, and the glucose contacting the analyte blood. In addition, Sun et al's implantable sensor includes detector for detecting optical properties of the probe (col. 10, lines 55-60), housing where the substrate, excitation source, probe, and detector are disposed (figure 4, col. 10, lines 60-67; col. 11, lines 43-67), and catheter with a lumen 22 (figure 6), extending at least through part of the length of the body-insertable apparatus, that infuses insulin.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 3, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* as applied to claims 1 and 44 above, and further in view of *Hunter et al* (US 5,716,981).

Kovac et al substantially disclose of all claimed features in claims 2, 3, 45, and 46. However, Kovac et al's disclosure does not include oligonucleotide or protein bounded to the

Art Unit: 3737

probe. Hunter et al teach that oligonucleotide or protein on substrate can be detected via radiation path, similar to radiation detection with substrate attached to a probe described by Kovac et al. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to adapt Hunter al's teaching of using oligonucleotide or protein substrate to detect radiation signal.

8. Claims 16 and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* as applied to claims 1 and 44 above, and further in view of *Salb* (US 5,408,996).

Kovac et al substantially disclose of all claimed features in claims 16 and 58, in addition to description above includes a transmission of detected signals to a remote reader (col. 6, lines 55-56) except that Kovac et al do not teach a display. However, it is well known in the art to one having an ordinary skill in the art of medical imaging to have display so one may observe diagnostic data image captured from the imaging apparatus. For example, Salb teaches a tissue diagnostic device wherein captured data from an optical detector is transmitted to a display.

9. Claims 24 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* as applied to claims 1, 23, 44, and 69 above, and further in view of *McGill et al* (US 5,412,087).

Kovac et al substantially disclose of all claimed features in claims 24 and 70, in addition to description above includes a filter (col. 5, line 25). However Kovac et al do not specifically disclose the filter as a band pass filter (BPF). McGall et al teach an analyte biosensor that uses a BPF (col. 14, line 30). Therefore it would have been obvious to one having an ordinary skill in the art a the time the invention was made adapt McGall et al's teaching of using BPF to detected optical signal to improve the reduction of noise.

Art Unit: 3737

10. Claims 27-30, 72, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* as applied to claims 1 and 44 above, and further in view of *Pizziconi et al* (US 4,832,034).

Kovac et al substantially disclose of all claimed features in claims 27, 29, 72, and 74 in addition to description above includes insertable catheter. However, Kovac et al do not anticipate the catheter with a lumen capable of withdrawing biosensing fluids for analysis. Pizziconi et al teach such a feature, in which filtrate is withdrawn from the body and placing it in contact with the sensors (col. 15, line 50). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to adapt Pizziconi et al's withdrawal of biosensing material for further analysis to improve Kovac et al's device.

Allowable Subject Matter

11. Claims 8-10, 12, 13, 49-53, 55, 56, 65, 75-79, and 81-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

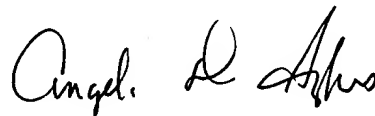
Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung whose telephone number is 703-605-4364. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

Art Unit: 3737

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

465
April 26, 2004



**ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**